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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/241,497 | 02/01/99 | HAMEL | M 4666 |

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IM52/0309

EXAMINER

SINES, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1743

DATE MAILED:

03/09/01

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/241,497

Applicant(s)

HAMEL ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Applicant has admitted that it is the dimensions and the inherent stiffness of the plate that combine to give the lack of displacement in response to the applied force (first paragraph of remarks in amendment, p. 2).

Claims 1 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is not clear how the force should be applied to determine if there is the required displacement at the "geometric center." For examination purposes, examiner is treating the claim as including applying the force on the inner region adjacent to the edge. In claim 1, the applicant should specify precisely where and how the force is applied within the inner region of the plate. Is the force applied evenly over the entire surface, at a point location within a corner or edge of the inner region, or at the geometric center of the plate? In addition, the applicant should clarify what is meant as the geometric center of the plate. Is the geometric center a point location or a specified area within the inner region of the plate? Claim 3 recites the limitation "polycarbonate" in line 1. There is insufficient antecedent basis for this

limitation in the claim. Should claim 3 be dependent upon claim 2 instead of claim 1? Finally, there is no structural definition to discern between the edge and the inner region of the plate. How is the meeting of the edge and the inner region of the plate structurally defined? If the applicant is intending for the U-shaped ledge to define this structure, it fails because the ledge is not a positively recited element of the pipette tip magazine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Taggart (US 5,882,603). Taggart discloses a disposable pipette tip rack or magazine. As shown in Figure 1, Taggart discloses a pipette tip rack or magazine comprising a rectangular plate or tip holder (10) with a flat upper surface, having an edge, which encloses an inner region containing an array of through-openings (11) for vertically receiving and retaining pipette tips (P). The plate (10) has a flat upper surface. The tip holder (10) is not free standing and therefore requires the support (14) for use. The tip holder (10) is inserted into and rests within the support (14). The edge of the tip holder (10) rests on the support planes (24a,b) or ledges of the support (14). The support additionally comprises a varying number of support members (32) which can provide

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additional support to the tip holder (10). Taggart recognizes that the support members (32) must have sufficient strength so that the tip holder (10) does not substantially deflect down or warp when the pipette tips (P) are removed by an instrument which presses down onto the apparatus within the geometric center so as to wedge the pipette tips (P) securely onto the pipetting instrument (lines 58 – 65, column 3). Due to the lack of clarity about how the force is applied and the structural definition of the edge of the plate, the claim is anticipated based upon the examiner's treatment of the scope.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rainin (US 4,577,760). Rainin et al. teach an apparatus for supporting pipette tips. As shown in figures 1 – 12, Rainin et al. teach a pipetting chamber (12) with a generally U-shaped ledge (90), a pipette tip magazine (22) adapted for insertion into and removal from an operative position in the chamber supported on the ledge (90). The magazine comprises a generally rectangular flat plate (22) having an edge (15) surrounding an inner region where the edge is configured to be supported on the ledge (90). The inner region has an array of through openings (118) for vertically receiving and retaining pipette tips (26, 28) (see Description of Preferred Embodiments section). The plate is manufactured from a polymeric resin (col. 4, lines 46 – 55). Due to the lack of clarity about how the force is applied and the structural definition of the edge of the plate, the claim is anticipated based upon the examiner's treatment of the scope.

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Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolp (US 56,309,980). Stolp teaches a pipette tip mounting and transfer apparatus. As shown in figures 1 – 4, Stolp teaches a pipetting chamber (56) with a generally U-shaped ledge, a pipette tip magazine (32) adapted for insertion into and removal from an operative position in the chamber supported on the ledge (90). The magazine comprises a generally rectangular flat plate (32) having an edge (52) surrounding an inner region (50) where the edge (52) is configured to be supported on the ledge (44). The inner region has an array of through openings (34) for vertically receiving and retaining pipette tips (12) (see Description of Preferred Embodiments section). The plate is manufactured from a polymeric resin (col. 8, lines 12 – 21). Due to the lack of clarity about how the force is applied and the structural definition of the edge of the plate, the claim is anticipated based upon the examiner's treatment of the scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taggart as applied to claims 1 and 5 above, and in view of Stolp and Weast et al. (1984). Taggart discloses a disposable pipette tip rack or magazine containing the structural features of your device as similarly described in the language of claim 1. As shown in Figure 1, Taggart discloses a pipette tip rack or magazine comprising a rectangular plate or tip holder (10) with a flat upper surface, having an edge, which encloses an inner region containing an array of through-openings (11) for vertically receiving and retaining pipette tips (P). The plate (10) has a flat upper surface. The tip holder (10) is not free standing and therefore requires the support (14) for use. The tip holder (10) is inserted into and rests within the support (14). The edge of the tip holder (10) rests on the support planes (24a,b) or ledges of the support (14). The support additionally comprises a varying number of support members (32) which can provide additional support to the tip holder (10). Taggart recognizes that the support members (32) must have sufficient strength so that the tip holder (10) does not deflect down or warp when the pipette tips (P) are removed by an instrument which presses down onto the apparatus within the geometric center so as to wedge the pipette tips (P) securely onto the instrument (lines 58 – 65, column 3). Although, Taggart teaches that a variety of suitable materials, such as various plastics, metals, ceramics and combinations of such materials, may be used in the construction of the support

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and tip holder, Taggart is deficient in identifying a specific plastic material (lines 39 – 51, column 4). Stolp recognizes that tip holders should be of a material and have a shape that will prevent warping as pressure is applied (col. 6, lines 8 – 21). As taught by Stolp for example, pipette tip racks are commonly manufactured using polymeric thermoplastic resins, such as molded polypropylene or other related pressure-resistant durable plastics (lines 12 – 21, column 8). Furthermore, as taught by Weast et al., the mechanical properties characteristic of polycarbonate thermoplastics are indicative of greater mechanical strength and stiffness in comparison to unmodified and copolymer polypropylene thermoplastics (pp. C-780 – 782). For example, the modulus of elasticity of unfilled polycarbonate thermoplastics is $290 - 325 \times 10^3$ psi, whereas the modulus of elasticity for unmodified polypropylene thermoplastics is much lower at $1.4 - 1.7 \times 10^3$ psi. In addition, the tensile strength of unfilled polycarbonate thermoplastics is 8,000 – 9,500 psi, whereas the tensile strengths of unmodified and copolymer polypropylene thermoplastics are lower at 4,300 – 5,500 psi and 2,900 – 4,500 psi, respectively. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a thermoplastic polymer resin having greater mechanical strength properties, such as a polycarbonate resin, instead of a less mechanically robust polymeric resin, such as a polypropylene resin, in order to manufacture a pipette tip magazine having the desired mechanical strength, inherent stiffness and deflection properties as stated in the claims. The courts have decided that selection of a known material based on its suitability for the intended use is within the ambit of one of ordinary skill in the art [In re Leshin, 125 USPQ 416 (CCPA 1960)].

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Stolp additionally teaches a disposable pipette tip rack which is stackable when filled with pipette tips and is a commonly found feature in the design of disposable pipette tip racks as shown in Figure 2. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to manufacture a disposable pipette tip magazine which was stackable when filled with pipette tips. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Taggart, Stolp, Rainin and Weast et al. in order to provide for the invention as specified in claims 2, 6 and 7.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taggart in view of Stolp and Weast et al. (1984) as applied to claims 1² and 5¹ above, and further in view of Marrocco, III et al. (U.S. Pat. No. 6,087,467). Taggart's disclosure is deficient in suggesting the inclusion of glass fiber within the polymer resin to form a robust fiber-polymer composite. In the design of a tip holder and support, which would have been more resilient to downward deflection, a stiffer material, such as a fiber-polymer resin composite, would have been considered by one of ordinary skill in the art. Marrocco, III et al. teach rigid rod polymers. Marrocco, III et al. discloses that high-performance fiber-polymer composites are rapidly achieving a prominent role in the design of industrial equipment. Composites fill the need for stiffness, strength and low weight that cannot be met by other materials (col. 1, lines 30 – 37). Marrocco, III et al. further discloses that these polymer materials may be used as a thermoplastic resin, which is pultruded with carbon or glass fibers (col. 21, lines 64 – 66). Additionally, the

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amount of glass fiber used within the polymer composite would have been considered a result effective variable, whose determination would have been within the ambit of one of ordinary skill in the art without undue experimentation, in order to acquire the necessary stiffness properties for the tip magazine. The courts have decided that the discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of one of ordinary skill in the art [In re Boesch, 205 USPQ 215 (CCPA 1980)]. Taggart, Stolp, Weast et al. and Marrocco, III et al. are considered analogous art since they are from the similar problem solving area involving material selection for apparatus manufacture based upon required physical properties. At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a polymer composite incorporating a glass fiber additive in an appropriate amount for the manufacture of a pipette tip magazine. The suggestion for doing so would have been derived from the motivation to obtain the required stiffness for the tip magazine. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Taggart, Stolp, Weast et al. and Marrocco, III et al. in order to provide for the invention as specified in claims 3 and 4.

Claims 2 – 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolp as applied to claims 1 and 5 above, and further in view of ~~Stolp~~ Weast et al. (1984) and Marrocco, III et al. (U.S. Pat. No. 6,087,467). Stolp's disclosure is deficient in suggesting a polycarbonate material or the inclusion of glass fiber within the polymer resin to form a robust fiber-polymer composite. In the design of

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a tip holder and support, which would have been more resilient to downward deflection, a stiffer material, such as a fiber-polymer resin composite, would have been considered by one of ordinary skill in the art. Marrocco, III et al. teach rigid rod polymers. Marrocco, III et al. discloses that high-performance fiber-polymer composites are rapidly achieving a prominent role in the design of industrial equipment. Composites fill the need for stiffness, strength and low weight that cannot be met by other materials (col. 1, lines 30 – 37). Marrocco, III et al. further discloses that these polymer materials may be used as a thermoplastic resin, which is pultruded with carbon or glass fibers (col. 21, lines 64 – 66). Additionally, the amount of glass fiber used within the polymer composite would have been considered a result effective variable, whose determination would have been within the ambit of one of ordinary skill in the art without undue experimentation, in order to acquire the necessary stiffness properties for the tip magazine. The courts have decided that the discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of one of ordinary skill in the art [In re Boesch, 205 USPQ 215 (CCPA 1980)]. Furthermore, as taught by Weast et al., the mechanical properties characteristic of polycarbonate thermoplastics are indicative of greater mechanical strength and stiffness in comparison to unmodified and copolymer polypropylene thermoplastics (pp. C-780 – 782). For example, the modulus of elasticity of unfilled polycarbonate thermoplastics is $290 - 325 \times 10^3$ psi, whereas the modulus of elasticity for unmodified polypropylene thermoplastics is much lower at $1.4 - 1.7 \times 10^3$ psi. In addition, the tensile strength of unfilled polycarbonate thermoplastics is 8,000 – 9,500 psi, whereas

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the tensile strengths of unmodified and copolymer polypropylene thermoplastics are lower at 4,300 – 5,500 psi and 2,900 – 4,500 psi, respectively. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a thermoplastic polymer resin having greater mechanical strength properties, such as a polycarbonate resin, instead of a less mechanically robust polymeric resin, such as a polypropylene resin, in order to manufacture a pipette tip magazine having the desired mechanical strength, inherent stiffness and deflection properties as stated in the claims. The courts have decided that selection of a known material based on its suitability for the intended use is within the ambit of one of ordinary skill in the art [In re Leshin, 125 USPQ 416 (CCPA 1960)]. Stolp additionally teaches a disposable pipette tip rack which is stackable when filled with pipette tips and is a commonly found feature in the design of disposable pipette tip racks as shown in Figure 2. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to manufacture a disposable pipette tip magazine which was stackable when filled with pipette tips. Stolp, Weast et al. and Marrocco, III et al. are considered analogous art since they are from the similar problem solving area involving material selection for apparatus manufacture based upon required physical properties. At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a polymer composite incorporating a glass fiber additive in an appropriate amount for the manufacture of a pipette tip magazine. The suggestion for doing so would have been derived from the motivation to obtain the required stiffness for the tip magazine. Therefore, it would have been obvious to one of ordinary skill in the art to combine the

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teachings of Stolp, Weast et al. and Marrocco, III et al. in order to provide for the invention as specified in claims 2 – 4, 6 and 7.

Response to Arguments

Applicant's arguments filed 1/27/2001 have been fully considered but they are not persuasive. With regard to the new anticipatory references, it is the applicant's burden to explain that a tip holder made according to either Stolp or Rainin does not inherently possess the required stiffness. The applicant states that the downward deflection of the plate resulting from the applied force is dependent upon both the stiffness of the material and the size dimensions of the plate. Therefore, claim 1 is incomplete since the properties and characteristics of the plate, namely size dimensions and material composition, which are deemed responsible for imparting the desired deflection characteristics, are not stated in the claim. Because of the lack of clarity in the claims regarding how the force is applied, the Taggart reference is deemed to anticipate the claimed property within the scope used by the examiner. Certainly, applying the force at a position adjacent to the supported edge would produce little if any deflection at the geometric center of the tip holder. Relative to the obviousness combination, both Taggart and Stolp recognize that the tip holder should be prevented from warping when pressure is applied. The Stolp reference shows that this may be done by the shape and material of the tip holder. Thus, it would have been obvious to one of ordinary skill in the art to modify Taggart to reduce the need for supporting the tip holder by using either a shape or material or both that would have given this ability to

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the tip holder. In conjunction with this modification, Weast et al. show that one of ordinary skill in the art would have recognized that plastics, such as polycarbonate have inherent properties of strength or stiffness, which exceed those of a material such as polypropylene. With regards to the specification of the structure of the edge of the plate, as shown in figure 1A of Stolp, an edge or lower surface (52) is used to define the area around the outer perimeter of the magazine. The edge region or lower surface (52) defines an inner region or upper surface (50) of a tip magazine (32). Contrary to the assertion of the applicants, the geometric center of the plate is not considered an inherent limitation. Is the geometric center a point location or a specified area within the inner region of the plate?

In response to applicant's argument that the prior art structure cannot be utilized in an automated pipetting system, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (703) 305-

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0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

BJS
March 8, 2001

Arleen Soderquist
ARLEEN SODERQUIST
PRIMARY EXAMINER